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| APPLICATION NO.                                   | FILING DATE                       | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|---|-----------------------------------|----------------------|-------------------------|------------------|
| 10/053,669  | 01/24/2002                        | Ibert C. Wells       | N1427-005               | 1066             |
| 27910   | 7590 07/16/2004                   |                      | EXAMINER                |                  |
| STINSON MORRISON HECKER LLP<br>ATTN: PATENT GROUP |                                   |                      | SZPERKA, MICHAEL EDWARD |                  |
|   | ENT GROUP<br>UT STREET, SUITE 280 | 00                   | ART UNIT                | PAPER NUMBER     |
| KANSAS CI   | TY, MO 64106-2150                 |                      | 1644                    |                  |
|   |                                   | •                    | DATE MAILED: 07/16/200- | 4                |

Please find below and/or attached an Office communication concerning this application or proceeding.

|   | Application No.  | Applicant(s)  |  |  |  |
|---|--|---|--|--|--|
|   | 10/053,669   | WELLS, IBERT C.   |  |  |  |
| Office Action Summary   | Examiner   | Art Unit  |  |  |  |
|   | Michael Szperka  | 1644  |  |  |  |
| The MAILING DATE of this communication ap<br>Period for Reply   | pears on the cover sheet w   | vith the correspondence address ~   |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPL THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.  after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a rep  - If NO period for reply is specified above, the maximum statutory period  - Fallure to reply within the set or extended period for reply will, by statut Any reply received by the Office later than three months after the mailine earned patent term adjustment. See 37 CFR 1.704(b). | 138(a). In no event, however, may a sky within the statutory minimum of thi will apply and will expire SIX (6) MO e, cause the application to become A | reply be timely filed  rly (30) days will be considered timely.  NTHS from the mailing date of this communication.  BANDONED (35 U.S.C. § 133). |  |  |  |
| Status  |  |   |  |  |  |
| 1) Responsive to communication(s) filed on 11/0   | 03/2003.   |   |  |  |  |
|   | s action is non-final.   |   |  |  |  |
| 3) Since this application is in condition for allowa  | · <u> </u>   |   |  |  |  |
| closed in accordance with the practice under  | Ex parte Quayle, 1935 C.[  | D. 11, 453 O.G. 213.  |  |  |  |
| Disposition of Claims   |  |   |  |  |  |
| 4)⊠ Claim(s) <u>1-17 and 21-23</u> is/are pending in the  | application.   |   |  |  |  |
| 4a) Of the above claim(s) is/are withdra  |  |   |  |  |  |
| 5) Claim(s) is/are allowed.   |  |   |  |  |  |
| 6) Claim(s) is/are rejected.  |  |   |  |  |  |
| 7) Claim(s) is/are objected to.   |  | •   |  |  |  |
| 8) Claim(s) 1-17 and 21-23 are subject to restrict  | tion and/or election require   | ement.  |  |  |  |
| Application Papers  | ·  |   |  |  |  |
|   |  |   |  |  |  |
| 9) The specification is objected to by the Examine  |  | buthe Evenines  |  |  |  |
| 10) The drawing(s) filed on is/are: a) acc  | • • • •  | ·   |  |  |  |
| Applicant may not request that any objection to the   |  |   |  |  |  |
| Replacement drawing sheet(s) including the correct  | •  |   |  |  |  |
| 11) The oath or declaration is objected to by the Ex  | xaminer. Note the attache  | d Office Action or form PTO-152.  |  |  |  |
| Priority under 35 U.S.C. § 119  |  |   |  |  |  |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  |  | § 119(a)-(d) or (f).  |  |  |  |
| 1. Certified copies of the priority documents have been received.   |  |   |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No  |  |   |  |  |  |
| <ol><li>Copies of the certified copies of the prio</li></ol>  | •  | received in this National Stage   |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).   |  |   |  |  |  |
| * See the attached detailed Office action for a list  | of the certified copies not  | received.   |  |  |  |
|   |  |   |  |  |  |
| Attachment(s)   |  |   |  |  |  |
| Notice of References Cited (PTO-892)  | ,  | Summary (PTO-413)<br>s)/Mail Date   |  |  |  |
| <ol> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)</li> <li>Paper No(s)/Mail Date</li> </ol>  | _ —  | nformal Patent Application (PTO-152)  |  |  |  |

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## **DETAILED ACTION**

Applicant's Preliminary Amendment filed 11/03/2003 is acknowledged.

Claims 18-20 have been cancelled.

Claims 21-23 have been added.

Claims 1-17 and 21-23 are pending.

## Election/Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - Claims 1-10, drawn to an antibody of high affinity for a peptide sequence, classified in Class 530, subclass 387.9.
  - II. Claims 11-17, drawn to a method of detecting magnesium binding defect, classified in Class 435, subclass 7.1.
  - III. Claims 21-23, drawn to a method of monitoring the progress of treatment of magnesium binding defect, classified in Class 436, subclass 86.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and (II and III) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of

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invention I could be used for western blotting rather than the methods of inventions II and III.

- 3. Inventions II and III are different methods. In the instant case monitoring the progress of treatment for magnesium binding defect involves steps
- 4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
- 5. This application also contains claims directed to patentably distinct species of the claimed inventions of Groups I-III as they read on the identity of the peptide chosen from the following:
  - a) Phe-Phe-Gly-Leu-Met-NH2,
  - b) Phe-Val-Gly-Leu-Met-NH2, or
  - c) Phe-Gly-Leu-Met-NH<sub>2</sub>.

These species are distinct because they differ in structure.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 11, and 21 generic for example.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

- 6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
- 7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Szperka, Ph.D. Patent Examiner Technology Center 1600 July 9, 2004

PHILLIP CAMBEL, PH.D
PRIMARY EXAMINER
TECH CEUTON 16 00

7/9/04